Full Text HD-93-011

# BIOMATERIALS TO RESTORE FUNCTION IN PEOPLE WITH PHYSICAL DISABILITIES

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P.T.

Keywords:

National Institute of Child Health and Human Development
National Institute of Arthritis and Musculoskeletal and Skin Diseases

Letter of Intent Receipt Date: April 26, 1992
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## PURPOSE

The National Center for Medical Rehabilitation Research (NCMRR) of the National Institute of Child Health and Human Development (NICHD) and the National Institute of Arthritis, Musculoskeletal and Skin Diseases (NIAMS) invite research grant applications to develop new biomaterials that will be used to improve function in people with physical disabilities. The goal of this RFA is to stimulate high risk, innovative research projects that will provide preliminary data leading to the development of novel materials designed to restore, improve, or enhance function lost as a consequence of injury, disease, or congenital disorder.

## HEALTHY PEOPLE 2000

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention goals of "Healthy People 2000," a PHS-led national activity for setting priorities. This Request for Applications (RFA), Biomaterials to Restore Function in People with Physical Disabilities, is related to the priority areas of chronic and disabling conditions and the goal to reduce health disparities among Americans. Potential applicants may obtain a copy of "Healthy

People 2000" (Full Report: Stock No. 017-001-00474-0, or Summary Report: Stock No. 017-001-00473-1) through the Superintendent of Documents, Government Printing Office, Washington, DC 20402-9325 (telephone 202-783-3238).

## ELIGIBILITY REQUIREMENTS

Applications may be submitted by domestic and foreign for-profit and non-profit organizations, public and private, such as universities, colleges, hospitals, laboratories, units of state and local governments, and eligible agencies of the Federal government. Women and minority investigators are encouraged to apply.

## MECHANISM OF SUPPORT

This RFA will use the National Institutes of Health (NIH) investigator initiated research project grant (R01) mechanism. Applications submitted in response to the present RFA may not exceed two years and the total direct costs for the first year may not exceed $50,000 and a total of $100,000. Responsibility for the planning, direction, and execution of the proposed project will be solely that of the applicant. The earliest anticipated award date will be September 1993. This RFA is a one-time solicitation. Future unsolicited competing continuation applications will compete with all investigator-initiated applications and be reviewed according to the customary NIH peer review procedures.

## FUNDS AVAILABLE

Applications submitted in response to this announcement will compete for direct costs of approximately $500,000 from the NICHD and $150,000 from the NIAMS that have been made available for this purpose in Fiscal Year 1993. It is expected that 10 awards will be made by the NICHD and three by the NIAMS. The number of awards depends upon the overall scientific merit of the proposals, their relevance to the stated goal of the announcement, and the availability of funds.

## RESEARCH OBJECTIVES

### Background

Between 35 and 43 million Americans have one or more conditions that result in a limitation of life activities. The annual disability-related costs to the nation are in excess of $170 billion.

These limitations may result from either injury, disease or birth defect.

During the past decade, remarkable advances have been made in biotechnology and in characterizing tissue interactions. These advances now permit the development of novel biocompatible materials that can lead to the restoration of function in persons with physical disabilities.

The goal of the NCMRR is to promote research that will lead to the replacement, enhancement or restoration of function in persons with physical disabilities in order to maximize their functional capabilities, both immediately after the onset of the disabling condition and throughout the lifespan. The NCMRR has identified seven research priority areas. This RFA will address three of these areas: the improvement of mobility, the whole body systems response to chronic injury, and advances in assistive technologies.

Included in the goals of the NIAMS are promoting and funding research on the basic biology, injury, and chronic diseases of structural and connective tissues, such as bone, muscle, ligament, tendon, cartilage, and skin. As such, research on novel biomaterials may be targeted to treatment of these conditions.

Scope

The purpose of this RFA is to develop a grant program that will provide funds to support exploratory studies leading to the development of novel genetically engineered biomaterials, to encourage research into the modification of biological products that can be used to stimulate the regeneration of tissues, and to produce delivery vehicles that will supply gene products necessary to maintain function or reduce the process of further injury.

The following list of topic areas, though not inclusive, serves as a guide for potential applications under this grant program:

o development of coating materials that will render implanted devices biocompatible

o development of modified extracellular matrix materials that can serve as substrates or scaffolding that will enhance regeneration of neurons, supporting cells, and other soft tissues after long-term injury

o development of ion-sensitive films/materials that can be attached to biological membranes to detect and enhance residual neuronal activity in chronically injured systems

o identification of novel biopolymers that can act as microcapsules to provide slow release of genetically modified gene products

o development of skin substitutes for healing of decubitus ulcers

o development of implantable or cutaneous biosensors to detect pressure and cutaneous breakdown

o modification of natural products to reduce scarring both in the nervous system and in soft tissues

o development of materials to immunologically isolate implanted materials

o development of genetically modified cell lines that can be introduced into sites of injury and tissue loss to stimulate regeneration of neurons, muscle, and connective tissues

o development of biomaterials that will improve sphincter function

STUDY POPULATIONS

SPECIAL INSTRUCTIONS TO APPLICANTS REGARDING IMPLEMENTATION OF NIH POLICIES CONCERNING INCLUSION OF WOMEN AND MINORITIES IN CLINICAL RESEARCH STUDY POPULATIONS

It is NIH policy that applicants for NIH clinical research grants will be required to include minorities and women in study populations so that research findings can be of benefit to all persons at risk of the disease, disorder or condition under study. Special emphasis should be placed on the need for inclusion of minorities and women in studies of diseases, disorders, and conditions that disproportionately affect them. This policy is intended to apply to males and females of all ages. If women or minorities are excluded or inadequately represented in clinical research, particularly in proposed population-based studies, a clear compelling rationale should be provided.

The composition of the proposed study population must be described in terms of gender and racial or ethnic group together with a rationale for its choice. In addition, gender and racial or

ethnic issues should be addressed in developing a research design and sample size appropriate for the scientific objectives of the study. This information should be included on the grant application form PHS 398 in Sections 1-4 of the research plan and summarized in Section 5, (Human Subjects).

Applicants are urged to carefully assess the feasibility of including the broadest possible representation of minority groups. However, NIH recognizes that it may not be feasible or appropriate in all research projects to include representation of the full array of United States racial or ethnic minority populations (i. e., Native Americans [including American Indians or Alaskan Natives, Asian/Pacific Islanders, Blacks, Hispanics].

The rationale for limiting studies to one minority population group should be provided.

For the purpose of this policy, clinical research includes human biomedical and behavioral studies on etiology, epidemiology, prevention (and preventive strategies), diagnosis, or treatment of diseases, disorders or conditions, including but not limited to clinical trials.

The usual NIH policies concerning research on human subjects also apply. Basic research or clinical studies in which human tissues cannot be identified or linked to individuals are excluded. However, every effort should be made to include human tissue from women and racial/ethnic minorities when it is important to apply the results of the study broadly, and this should be addressed by applicants.

For foreign awards, the policy on inclusion of women applies fully; since the definition of minority differs in other countries, applicants must discuss the relevance of research involving foreign population groups to the United States populations, including minorities.

Peer reviewers will address specifically whether the research plan in the application conforms to these policies. If the representation of women or minorities in a study design is inadequate to answer the scientific question(s) addressed and the justification for the selected study population is inadequate, it will be considered a scientific weakness or deficiency in the study design and will be reflected in assigning the priority score to the application.

All applications for clinical research submitted to NIH are required to address these policies. NIH funding components will not award grants or cooperative agreements that do not comply with these policies.

## LETTER OF INTENT

Potential applicants are strongly encouraged to submit a letter of intent by April 26, 1993. The letter of intent is requested for planning purposes only and should include: the name of the Principal Investigator, a descriptive title of the potential application, identification of the organization involved and the RFA number and title. The letter of intent is to be addressed to Dr. Danuta Krotoski at the address listed under INQUIRIES.

## APPLICATION PROCEDURES

Applications are to be submitted on form PHS 398 (rev. 9/91). This application form is available in the business or grants and contracts office at most academic and research institutions and from the Office of Grants Inquiries, Division of Research Grants, National Institutes of Health, Westwood Building, Room 449, Bethesda, MD 20892, telephone (301) 496-7441.

The receipt deadline for applications prepared in response to this RFA is May 25, 1993. Late applications will not be accepted. This is a one-time announcement.

The RFA label available in the application kit must be affixed to the bottom of the face page. Failure to use this label could result in delayed processing of the application in that it may not reach the review committee in time for evaluation.

Check "yes" in item 2a on the face sheet of the application and type "Biomaterials to Improve Function in People with Physical Disabilities." The outside of the application packages should also be marked "Response to RFA HD-93-011. The original and three copies of the application must be sent or delivered to:

Division of Research Grants
National Institutes of Health
Westwood Building, Room 240
Bethesda, MD 20892**

In addition, two copies of the application must be sent under separate cover to:

Susan Streufert, Ph.D.
Acting Director, Division of Scientific Review
National Institute of Child Health and Human Development

6100 Executive Boulevard, Room 5E03F
Rockville, MD 20892

REVIEW CONSIDERATIONS

Applications will be reviewed by staff of the NICHD for responsiveness to the RFA. Applications deemed non-responsive will be returned to the applicant. In the event that an application is returned, the applicant has the option to resubmit it for review in competition with unsolicited applications at the next review cycle. The DRG will not accept any application in response to this announcement that is essentially the same as one currently pending initial review, unless the applicant withdraws the pending application. The DRG will not accept any application that is essentially the same as one already reviewed. This does not preclude the submission of substantial revisions of applications already reviewed, but such applications must include an introduction addressing the previous critique.

Responsive applications may be evaluated by a preliminary triage in a peer review group to determine their scientific merit relative to other applications received in connection with this RFA. NIH staff will withdraw from competition those applications judged to be non-competitive. The Principal Investigator and his/her institutional business official will be notified in such instances. Those applications judged to be competitive will be further evaluated for technical and scientific merit by a special review panel convened for this purpose by the Division of Scientific Review, NICHD.

Review criteria will be those normally used by the NIH to evaluate investigator-initiated research grant applications, including:

o Thorough knowledge of scientific literature in appropriate fields

o Scientific, technical, or medical significance and originality of proposed research

o Appropriateness and adequacy of the experimental approach and methodology proposed to carry out the research

o Qualifications and research experience of the Principal Investigator and staff, particularly but not exclusively in the area of the proposed research

o Availability of resources necessary to perform the research

o  Appropriateness of the proposed budget and duration in relation to the proposed research

Following the initial review by the special review committee, all applications will be reviewed by the NICHD or NIAMS National Advisory Councils.

AWARD CRITERIA

Awards will be made on the basis of the quality of the proposed project as determined by peer review, program balance among research areas, and level of funding set aside for this RFA.

INQUIRIES

Requests for additional information and descriptions of proposed research projects may be directed to:

Danuta Krotoski, Ph.D.
Chief, Basic Rehabilitation Medicine Research Branch
National Institute of Child Health and Human Development
Executive Plaza South, Room 450W
Bethesda, MD  20892
Telephone:  (301) 402-2242

or

Stephen Gordon, Ph.D.
Chief, Musculoskeletal Diseases Branch
National Institute of Arthritis and Musculoskeletal and Skin Diseases
Westwood Building, Room 407
Bethesda, MD  20892
Telephone:  (301) 402-3338

For fiscal and administrative inquires, applicants may write or call:

Mary Ellen Colvin
Office of Grants and Contracts
National Institute of Child Health and Human Development
6100 Executive Boulevard, Room 8A17F

Bethesda, MD  20892
Telephone:  (301) 496-1303

or

Carol Clearfield
Grants Management Branch
National Institute of Arthritis and Musculoskeletal and Skin Diseases
Westwood Building, Room D
Bethesda, MD  20892
Telephone:  (301) 402-3360

AUTHORITY AND REGULATION

This program is described in the Catalog of Federal Domestic Assistance No. 93.929 (Medical Rehabilitation Research) and 93.846 (Arthritis and Musculoskeletal and Skin Disease Research). Awards are made under authorization of the Public Health Service Act, Title IV, Part A (Public Law 78-410, as amended by Public Law 99-158, 42 USC 241 and 285) and administered under PHS grants policies and Federal Regulations 42 CFR 52 and 45 CFR Part 74. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

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